

Non-Invasive Pressure Support Ventilation in Major Lung Resection for High Risk Patients: Does It Matter?

Bernhard C. Danner^{1*}, Wolfgang Koerber^{2*}, Alexander Emmert¹, Ulrike Olgemoeller³, Hilmar Doerge¹, Michael Quintel³, Carl-P. Criée², Friedrich A. Schoendube¹

¹Department of Thoracic and Cardiovascular Surgery, University Medical Centre Göttingen, Göttingen, Germany; ²Department of Pneumology, Respiratory Care and Sleep Medicine, Evangelical Hospital Weende, Göttingen, Germany; ³Department of Anaesthesiology, Emergency and Intensive Care, University Medical Centre Göttingen, Göttingen, Germany.

Email: bernd.danner@med.uni-goettingen.de

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ABSTRACT

Background and purpose: Patients with severely impaired pulmonary function have an increased operative risk for major lung resection. The clinical benefits of pre- and perioperative, non-invasive pressure support ventilation (NIPSV) have up to now not been extensively evaluated. Patients with severely reduced pulmonary function were investigated in this prospective and randomised single centre clinical trial. **Methods:** Standard pulmonary evaluation was performed in all patients before major lung resection. To predict postoperative pulmonary function, a lung perfusion-ventilation scan was carried out. All patients enrolled in the study were instructed preoperatively on how to use a NIPSV respirator. After lung resection patients were randomised either for continuation of NIPSV or for standard treatment. **Results:** Of the 52 patients assessed, 21 patients met the inclusion criteria for the study protocol. Predicted mean postoperative FEV₁ was 1.10 L (range 0.92 - 1.27 L). Lobectomy was performed in 14 patients, pneumonectomy in 6 patients and a segmentectomy in 1 patient. No inhospital deaths occurred. Pulmonary complications (reintubation, pneumonia) were more frequent in the NIPSV group than in the control group (3 patients versus 1 patient), without statistical significance ($p = 0.31$). **Conclusions:** We observed no mortality and a low morbidity in this high risk group. Postoperative continuation of NIPSV had no beneficial effect on the clinical outcome. Preoperative conditioning with NIPSV, however, seems to be a suitable tool for patients with severely impaired pulmonary function. This study may serve therefore as basis for further investigations for the potential clinical benefits of prophylactic NIPSV in major lung surgery.

Keywords: Chronic Obstructive Lung Disease; Clinical Trial; Non-Invasive Positive-Pressure Ventilation; Thoracic Surgery

1. Introduction

In major lung surgery, postoperative mortality for pneumonectomy is approximately 11.5% and for lobectomy 4% [1]. Decrease in the mortality rate in recent years is mainly a consequence of lower rates of pneumonectomy [2]. Nevertheless, pneumonia and acute respiratory failure are the main causes of postoperative death in about 46% of patients [2]. Especially in patients with reduced forced expiratory volume at one second (FEV₁) and diffusing lung capacity for carbon monoxide (DL-CO), postoperative mortality and morbidity increases inversely proportional to lung function [3-7]. Non-invasive pressure support ventilation (NIPSV) is a mode of mechanical ventilation without endotracheal intubation [8]. Either a certain tidal volume (volume controlled modus) or a maximal inspiratory pressure (pressure con-

trolled modus) is applied via a facial or nasal mask. In the volume controlled modus the ventilator determines the inspiratory pressure, whereas in the pressure controlled modus the tidal volume is determined by the ventilator depending on the pulmonary compliance. During the inspiratory cycle a full respiratory support to patient given. Application of a positive end-expiratory pressure (PEEP) results in a bilevel positive airway pressure mode. NIPSV has several advantages: avoidance of endotracheal intubation and consecutive analgesic sedation with its hemodynamic deterioration; preservation of daily activities as swallowing, coughing, and mobility; reduction of potential morbidity such as nosocomial pneumonia and upper airway trauma [9]. Especially for exacerbation of severe chronic obstructive pulmonary disease (COPD) it has been found to be superior [10,11]. In thoracic surgery NIPSV has therapeutic benefits for acute respiratory failure after major lung resection, consecu-

*Authors contributed equally to this work.

tively reducing mortality [12]. In using as a prophylaxis, NIPSV was found to improve functional lung parameters and arterial oxygenation [13,14]. Nevertheless, there are potential adverse side effects, e.g. hemodynamic impairment, aspiration, discomfort and pneumothorax [9].

Smokers are at high risk for bronchial carcinoma and the development of COPD [15]. Patients with indication for major lung resection and severe COPD are challenging in perioperative management [3]. Postoperative pneumonia and acute respiratory failure are main causes of death in patients with severe COPD [16]. To date, there are no clinical concepts to reduce these fatal complications in a prophylactic manner. Only limited data are available on clinical outcome and the prophylactic use of NIPSV in patients with severely impaired pulmonary function who undergo major lung resection. Therefore, we conducted a prospective clinical trial to investigate the effects of NIPSV in this high risk patient population. The aim of the study was to include only patients with persistent severely reduced pulmonary function after maximal conservative therapy.

2. Patients and Methods

All patients were presented in our comprehensive thoracic tumour board, consisting of pulmonologists, thoracic surgeons, medical and radiation oncologists. For each patient a therapeutic strategy was determined by this interdisciplinary team approach. Patients with severely impaired pulmonary function and indication for major lung resection were assessed for eligibility for the study protocol.

2.1. Study Protocol

All spirometric data were analysed after a post-bronchodilator test. Maximal medication comprising β_2 -agonist, anticholinergics, corticosteroids, theophylline and antibiotics were given for amelioration of the severely impaired pulmonary function. Repeated spirometry was carried out for optimisation of medical treatment. When functional parameters remained severely impaired, indicating a persistent high risk profile according to the British Thoracic Society guidelines [17], patients were included in the study protocol. The main inclusion criterion was a predicted postoperative (ppo) FEV₁ between 0.9 - 1.2 L. Exclusion criteria were FEV₁ under 0.9 L, maximal oxygen uptake lower than 10 ml per min per kg body weight, unstable coronary artery disease, preoperative necessity for invasive ventilation and a Karnofsky index of less than 60%. The preoperative NIPSV protocol was applied in all patients who were then transferred to the thoracic surgery unit. After major lung resection and extubation, patients were prospectively randomised either for continuation of NIPSV (NIPSV group) or for stan-

dard care (control group). The ethics committee of the university medical centre of Göttingen approved the study and informed consent of all patients was obtained (German clinical trial registry DRKS-ID 00000311).

2.2. NIPSV Protocol

For pulmonary conditioning all patients were instructed in use of non-invasive pressure support ventilation (NIPSV) before undergoing lung resection. A non-invasive ventilator (VS Ultra, Take Air Medical, Bremen, Germany) was used either in a pressure or a volume-controlled mode as the patient found most comfortable and 85% favoured the pressure-controlled mode. A nasal mask or a facial mask was adjusted. Tidal volume, maximum inspiration pressure, positive end expiratory pressure and ventilation frequency was adjusted individually to reach normocapnia and an oxygen saturation of more than 92%. After instruction and adaption under hospital conditions, the patients used NIPSV autonomously, applying it for a mean of 5.3 ± 3.2 hours per day preoperatively. Tidal volume was mean 8.3 ml per kg, the maximum pressure at a mean level of 16 mbar, and respirator frequency was mean 17 breaths per min. Mean inspiration time was 1.2 seconds, and four patients received a positive end expiratory pressure of 4 mbar. Additionally, all patients underwent an extended physiotherapeutic and medical optimising program. Postoperatively, after randomisation NIPSV was utilised by the patients autonomously and they were instructed to use the ventilator for 10 hours (intermittent or continuous) in the course of two consecutive days and for another 6 hours on the third day. In the control group patients were instructed not to use NIPSV; however, its use was not totally restricted due to ethical considerations.

2.3. Pulmonary Function Assessment

For evaluation a lung perfusion-ventilation scan was performed to calculate ppoFEV₁ using the equation: $\text{ppoFEV}_1 = \text{preoperative FEV}_1 \times (\text{1-proportion of perfused lung area to be resected})$ [17,18]. PH and blood gas measurements were quantified using a Ciba Corning blood gas analyser 855 (Ciba Corning Diagnostics, Medfield, USA). Further testing included evaluation of cardiopulmonary fitness by spiroergometry as well as respiratory muscle testing, diffusing capacity for carbon monoxide (DLCO) and arterial blood gas analysis on room air. For respiratory muscle testing (measurement of PI_{max} (kpa), P_{0.1} (kpa), and P_{0.1/P_{max}} (%), respectively), a ZAN 400 and for spiroergometry a ZAN 600 (nSpire-health, Oberthulba, Germany) were used. The range of normal values was defined according to the recommendations of the German Airway League and the ATS/ERS statement on respiratory muscle testing [19,20] as P_{0.1}

0.1 - 0.15 kpa, and PI_{max} 8.5 kpa for women and 11.5 kpa for men. Relevant fatigue of the inspiratory muscles was considered present at a PI_{max} of 7 kpa for women and 8 kpa for men.

2.4. Perioperative Care

Surgery was performed under standardised conditions by antero-axillary or antero-lateral thoracotomy. For pain management, an epidural catheter was the main method for analgesia; alternatively, a percutaneous blood pump was applied. Extubation was performed in accordance with the guidelines of the American College of Chest Physicians [21] either in the operating theatre or in the intensive care unit (ICU). Arterial and venous blood gas analyses, heart and respiratory rate, blood pressure and blood lactate concentration were measured every 4 hours after admission to the ICU. Laboratory blood tests, vital parameters and procedure-related measurements were carried out daily. Pain was measured four times per day on the basis of the analogue pain scale (range 0 to 10). All patients received standardised postoperative management including pain control, chest physiotherapy, early mobilisation and breathing exercises.

2.5. Randomisation

Randomisation was done by having the patients of the study group draw from prepared, sealed envelopes. Immediately afterward, the lung resection patients were randomly assigned to the NIPSV group or to the control group.

2.6. Definition of Endpoints

Primary endpoint was defined as pulmonary complications, including tracheal reintubation, inhospital death and pneumonia. Inhospital mortality was defined as death during periprocedural stay or within 30 days. Patients were defined as having postoperative pneumonia if they met the criteria set by the Centres of Disease Control and Prevention for nosocomial pneumonia after surgery: these are 1) presence of new and persistent lung infiltrate or 2) purulent tracheal secretion with positive microbial findings [22,23]. Reintubation was performed when one major criterion (respiratory arrest, respiratory pauses with loss of consciousness or gasping respiration) or two minor criteria (20% increase in arterial carbon dioxide tension, respiratory acidosis under pH 7.3, tachypnoe over 25 breathes per minute, respiratory fatigue or hemodynamic instability) were fulfilled. Secondary endpoints were length of stay at the intensive care unit (ICU), the normal ward of the department of thoracic surgery and total inhospital stay.

2.7. Statistics

The data are presented as mean with standard deviation for continuous variables, for categorical variables as proportion (%) or number (n). Differences in continuous variables were analysed by the Mann Whitney U-Test, in cases of equal variances by the independent t-test. For categorical variables the Fisher's exact test was used. For comparing between groups and at different times, a repeated analysis of variance (ANOVA) was performed. Results were considered significant if p values were 0.05 or less. Assuming that NIPSV is highly effective, already a sample size of 10 patients would reveal a power of 80%. For statistical analysis the SPSS® statistical software (SPSS 15.0 for Windows Evaluation Version, SPSS Inc., Chicago, Illinois, United States) was used.

3. Results

3.1. Preoperative Assessment

From 52 patients assessed for eligibility, 31 patients did not meet the inclusion criteria or refused to participate. Of the 21 patients in whom the inclusion criteria were met, 10 were randomly selected for the NIPSV group and 11 for the control group. Patients were recruited between April 2005 and June 2009.

Overall mean absolute ppoFEV₁ was 1.11 ± 0.1 L and mean relative ppoFEV₁ was $42.1\% \pm 9.5\%$. Preoperative data for the NIPSV and control groups are given in **Table 1** (clinical characteristics) and **Table 2** (cardiopulmonary function). There were no differences between the groups, except for the relative FEV₁ value and subsequently the ppoFEV₁ and the predictive postoperative product (PPP), as well as age (**Tables 1** and **3**).

3.2. Postoperative Data

Measurements of blood gas exchange, vital parameters, chest tube duration and drainage, analogue pain scale, laboratory blood tests, renal function, oxygen consumption or the need for catecholamine did not show a significant difference between the two groups. Blood gas analyses did not differ between the NIPSV or control group, neither between the groups nor between different time points. Oxygen delivery was unrestricted and blood gas exchange was measured according to the time intervals as stated above, independent of NIPSV utilisation. The use of NIPSV in each of the groups was significantly different in accordance with the study protocol. In **Table 4**, a synopsis of postoperative data measurement is shown.

3.3. Primary and Secondary Endpoints

No inhospital death occurred. Overall pulmonary complications were observed in 4 patients (19%) and were seen more often in the NIPSV group (3 patients, 30%)

Table 1. Clinical characteristics.

Clinical characteristics	NIPSV n = 10	Control group n = 11	p-value
Age (years)	71.1 ± 7.7	63.4 ± 5.9	0.016
Female gender (n)	3 (30%)	2 (18%)	0.635
Body mass index ($\text{kg} \cdot \text{m}^{-2}$)	29.4 ± 8.1	25.4 ± 5.4	0.223
Arterial hypertension	6 (60%)	5 (45%)	0.670
Coronary artery disease	2 (20%)	5 (45%)	0.361
Left ventricular function (ejection fraction %)	57.2 ± 10.8	48.7 ± 10.6	0.340
Diabetes mellitus	2 (20%)	3 (27%)	1.000
Creatinine kinase (mmol l^{-1}) (mg dl^{-1})	83.1 ± 29.1 0.94 ± 0.33	88.4 ± 17.7 1.00 ± 0.20	0.222
Previous thoracic surgery	1 (10%)	1 (9%)	1.000
Karnofsky index (%)	80.0 ± 10.5	82.7 ± 9.0	0.546
Oncologic disease	9 (90%)	11 (100%)	0.476
Chronic obstructive pulmonary disease (GOLD Classification)			
Stage 1	3 (30%)	0 (0%)	
Stage 2	5 (50%)	8 (73%)	
Stage 3	2 (20%)	3 (27%)	0.222
Nicotine consumption (pack years $^{-1}$)	40.0 ± 20.7	35.7 ± 12.3	0.738
Type of surgery			
Pneumonectomy	3 (30%)	3 (27%)	
Bi- or Lobectomy	7 (70%)	7 (64%)	
Segmentectomy	0 (0%)	1 (9%)	1.000
Extended surgical procedures	5 (50%)	5 (45%)	1.000
Operation time (min)	185 ± 31	117 ± 38	0.467
Single lung ventilation (min)	90 ± 22	84 ± 46	0.799
Thoracic epidural analgesia	6 (60%)	7 (64%)	1.000

Table 2. Preoperative functional parameters.

Preoperative functional parameters	NIPSV n = 10	Control group n = 11	p-value
Arterial blood gases (room air)			
pH	7.43 ± 0.03	7.43 ± 0.03	0.826
PaO ₂ (kPa) (mmHg)	9.5 ± 1.4 71.7 ± 10.7	8.5 ± 1.2 64.1 ± 8.7	0.152
PaCO ₂ (kPa) mmHg)	5.1 ± 0.5 38.6 ± 3.5	5.1 ± .5 38.5 ± 4.0	0.668
Vital capacity (litres)	2.45 ± 0.67	2.77 ± 0.95	0.323
Vital capacity (%)	68.9 ± 12.2	67.2 ± 16.2	0.717
Residual volume (litres)	3.00 ± .088	3.70 ± 1.52	0.323
Residual volume (%)	120.7 ± 30.5	167.1 ± 63.2	0.081
FEV ₁ (litres)	1.49 ± 0.28	1.37 ± 0.21	0.257
FEV ₁ (%)	60.2 ± 11.1	46.8 ± 10.4	0.021
Maximum oxygen uptake			
ml · kg $^{-1}$ · min $^{-1}$	17.1 ± 4.9	15.4 ± 3.8	0.364
%	58.7 ± 15.7	58.9 ± 10.1	0.793
DLCO (mmol · min $^{-1}$ · kPa $^{-1}$)	5.1 ± 1.2	4.9 ± 1.7	0.563
DLCO (%)	64.3 ± 15.6	54.8 ± 17.8	0.283
PI _{max} (kPa)	5.8 ± 1.5	4.7 ± 2.8	0.165
P _{0.1} · PI _{max} $^{-1}$ (%)	11.2 ± 10.7	11.0 ± 6.0	0.667

Abbreviations: PaO₂ = arterial oxygen tension; PaCO₂ = arterial carbon dioxide tension, FEV₁ = forced expiratory volume at 1 second; DLCO = diffusing capacity for carbon monoxide; P_{0.1} = airway pressure at 0.1 second; PI_{max} = maximum inspiratory pressure.

Table 3. Predicted postoperative functional parameters.

Postoperative predicted values	NIPSV n = 10	Control group n = 11	p-value
V/Q Scan-Proportion resected (%)	19.2 ± 11.8	20.2 ± 8.9	0.512
Predicted FEV ₁			
litres	1.15 ± 0.91	1.08 ± 0.11	0.230
%	48.7 ± 8.9	36.7 ± 6.3	0.004
Predicted DLCO			
mmol·min ⁻¹ ·kPa ⁻¹	4.00 ± 1.00	3.98 ± 1.14	0.888
%	51.7 ± 13.8	44.6 ± 12.4	0.515
Predicted Vital capacity			
litres	1.96 ± 0.59	2.22 ± 0.88	0.654
%	55.6 ± 12.9	52.8 ± 10.0	0.756
Predicted postoperative product			
(ppoFEV ₁ % · ppoDLCO%)	2566 ± 769	1661 ± 517	0.015
Predicted maximal oxygen uptake			
ml·kg ⁻¹ ·min ⁻¹	14.2 ± 4.9	12.1 ± 2.9	0.475
(%)	47.5 ± 11.9	46.1 ± 7.2	0.475

Abbreviations: PaO₂ = arterial oxygen tension; PaCO₂ = arterial carbon dioxide tension, FEV₁=forced expiratory volume at 1 second; DLCO = diffusing capacity for carbon monoxide; P_{0.1} = airway pressure at 0.1 second; PI_{max} = maximum inspiratory pressure, V/Q = ventilation/perfusion..

Table 4. Measurements of postoperative data.

Postoperative data	NIPSV n = 10	Control group n = 11	p-value
Oxygen application (litres·minute ⁻¹)			
Day 0	4.7 ± 2.4	6.2 ± 3.5	0.439
Day 1	3.6 ± 2.3	3.1 ± 3.0	0.503
Day 2	3.1 ± 1.8	3.7 ± 3.7	0.793
Analogue Pain Scale (0-10)			
Day0	Time 1 2.0 ± 1.6 Time 2 2.9 ± 1.5 Time 3 2.6 ± 1.2 Time 4 2.3 ± 1.3	2.9 ± 1.5 4.0 ± 1.8 3.6 ± 1.1 3.5 ± 2.1	0.180 0.158 0.057 0.112
Day1	Time 1 2.8 ± 0.9 Time 2 3.1 ± 0.8 Time 3 3.2 ± 1.0 Time 4 3.0 ± 0.7	3.0 ± 1.1 3.3 ± 1.1 3.4 ± 1.1 3.0 ± 1.2	0.834 0.860 0.804 0.827
Day2	Time 1 2.3 ± 0.5 Time 2 2.8 ± 0.8 Time 3 2.7 ± 0.7 Time 4 2.5 ± 0.8	3.1 ± 1.9 3.2 ± 1.0 2.9 ± 0.9 2.6 ± 07	0.395 0.403 0.704 0.893
Chest tube (days)	5.0 ± 4.0	5.5 ± 2.9	0.863
NIPSV postoperative (hours·day ⁻¹)			
Day 0 (day of surgery)	6.8 ± 5.5	0.6 ± 1.4	<0.001
Day 1	7.7 ± 3.9	0.4 ± 0.9	0.002
Day 2	5.9 ± 4.1	0.4 ± 1.0	0.001
Total	25.6 ± 14.8	2.2 ± 3.8	<0.001

Abbreviations: NIPSV=Non-invasive pressure support ventilation.

versus the control group (1 patient, 9%), but the difference was insignificant ($p = 0.31$). Tracheal reintubation due to respiratory insufficiency was necessary in 2 patients of the NIPSV group versus 1 patient in the control group. Nosocomial pneumonia occurred in 3 patients in the NIPSV group. Length of stay at the intensive care unit, length of stay at normal ward and total length of hospital stay (including rehabilitation) was not different between the two groups. All primary and secondary endpoint parameters are presented in **Table 5**.

Patients who underwent reintubation could be weaned from respirator and discharged from the hospital. Unsurprisingly, the mean time of hospital stay was significantly longer in these cases compared to uncomplicated cases (48.5 ± 13.7 versus 18.2 ± 9.7 days, $p = 0.002$). Prediction of pulmonary complications by the functional pulmonary parameters (see **Table 3**) failed, whereas pulmonary complications were significantly associated with a longer operation time (220 versus 172 min, $p = 0.009$).

4. Discussion

Extensive lung function assessment for patients with a higher risk of major lung resection is recommended by guidelines [4,17] and decreases postoperative morbidity and mortality [24]. Poor pulmonary function parameters are strongly correlated with increased postoperative morbidity and mortality [1,25-27]. In prospective studies, even with good pulmonary function the mortality rate for major lung resection was 2.7% - 4% and morbidity rate

was up to 41%. In these studies, measurement of immediate postoperative pulmonary function was 11% less than predicted, indicating an additional postoperative worsening, and improvement was seen after a period of 3 months for lobectomy only [28,29].

In major lung resection NIPSV has a positive effect on surrogate parameters, showing improved gas exchange, as well as on recruitment of atelectasis [13,14]. In patients with severely impaired cardio-pulmonary function the effects of prophylactic pre- and postoperative use of NIPSV on clinical outcome have not been previously investigated. Therefore, we conducted this randomised clinical trial to evaluate the potential beneficial effects of these surrogate parameters on overall clinical outcome, especially considering pulmonary complications.

There are several advantages to the use of NIPSV preoperatively. First, in a stressful situation such as acute dyspnoea, nasal or facial masks are not well tolerated, with a patient refusal rate of approximately 34% [30]. Preoperative introduction, training and familiarisation with ventilator support makes patients confident when using the mask even in uncomfortable circumstances. Second, NIPSV is superior to continuous positive airway pressure for preventing atelectasis [31], and furthermore, pulmonary functional parameters, especially oxygenation, were found to improve by the use of NIPSV. Although our patients were well instructed in autonomous use of NIPSV, patients generally have to be motivated postoperatively, sometimes intensively, which can result in a

Table 5. Primary and secondary outcome parameters.

Clinical outcome variable	NIPSV n = 10	Control group n = 11	Confidence Interval	p-value
Pulmonary complications (n)	3 (30%)	1 (9%)	0.4 - 50.2	0.311
Inhospital death	0	0		
Reintubation (n)	2 (20%)	1 (9%)	0.2 - 32.8	0.586
Pneumonia (n)	3 (30%)	0		0.090
ICU stay (days)	1.7 ± 1.6	2.8 ± 5.4	-2.6 - 4.8	0.777
Normal ward stay (days)	12.6 ± 3.8	13.7 ± 5.8	-25.7 - 4.4	0.723
Hospital-stay (days)	28.8 ± 19.9	18.9 ± 9.0	-3.4 - 5.7	0.306

Abbreviations: NIPSV = Non-invasive pressure support ventilation, ICU = Intensive Care Unit, n = number.

reduced utilisation time of the ventilator. However, the target overall ventilation time in the NIPSV group was met after 3 days. Possible undesired negative effects such as alterations of hemodynamics, appearance of bronchopleural fistula or bronchial stump insufficiency have to be taken into consideration [13,14], as well as the limited or disputable benefit of surgical resection in expected high operative risk [32,33].

Particularly the group with reduced lung capacity bordering on inoperability was the target group of our investigation. No single parameter for operative risk prediction exists, but there are several recommendations [4,25,34]. Severe reduction of FEV₁ was the main inclusion criterion for our study. The absolute value was chosen in the planning phase [17]; nowadays, it would be more reasonable to use parameters such as PPP (product of ppoFEV₁% and ppoDLCO%) which take both main predictors into account. Hence, the lower the PPP, the higher the operative risk probability [6]. Despite randomisation, the NIPSV group had improved pulmonary parameters (ppoFEV₁ and PPP) and the patients were older compared to the control group. The incidence of pneumonia was higher in the NIPSV group, possibly due to the higher mean patient age. In fact, contrary to our hypothesis that postoperative NIPSV has a beneficial effect, other negative side effects of positive pressure ventilation than mentioned above may result in a worse postoperative course. However, the endpoints were not statistically different between the groups. Although the functional parameters in prospective studies were tremendously improved compared to our study, mortality and morbidity remained high (4% and 41%, respectively) [28,29]. The absence of perioperative death as well as the low morbidity in this high risk patient cohort was possibly due to the preoperative conditioning of the patients for use of NIPSV. This may have already improved pulmonary function, lung compliance and muscle force. Since the pulmonary function parameters were significantly decreased in the control group and the pulmonary complications were low, a beneficial effect of preoperative conditioning with NIPSV seems likely.

Pulmonary function testing to predict postoperative function is extensive and time-consuming, particularly in patients with severely impaired pulmonary function. In retrospective studies, the predicted pulmonary function is inaccurate due to resection of tumourous or non-efficient lung parenchyma, which limits the interpretation of the results for predicting operative risk [25,35,36]. To exclude this bias we validated the predicted lung function by a ventilation-perfusion scan. In our study, only patients with accurately evaluated ppoFEV₁ were included; the majority of patients were excluded because of false underestimation of ppoFEV₁ either due to standard (segmental) calculated estimation or to improved FEV₁

through intensive pulmonary care. According to statistical power analysis, our study dealt with an adequate number of patients, but allows qualified interpretation of results only for powerful effectiveness of NIPSV. Nevertheless, a higher sample number and a modified study design would most likely provide more conclusive data on the prophylactic use of NIPSV.

5. Conclusion

In contrast to the expected operative risk in patients with severely impaired pulmonary function, in our present study pulmonary morbidity was low and no mortality occurred. Although postoperative continuation of NIPSV had no strong effect on the rate of pulmonary complications, preoperative application of NIPSV may have had a positive effect on postoperative outcome. This investigation can serve as a pilot study for an expanded multicentre investigation to evaluate the potential use of NIPSV for decreasing perioperative risk in patients with severely reduced lung function.

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